

USSN: 09/854,824

Docket No.: 56466US002

**REMARKS**

Claims 1-39 are pending in the application. Claims 1, 3, 11-13, 15, 30, 36-38 have been amended. Support for the amendment can be found on pages 4, lines 20-25; page 7, lines 8-9; and page 10, lines 27-28.

**Claim Rejections Under 35 U.S.C. § 102(b)**

The Examiner has indicated that the rejections under 35 U.S.C. § 102(b) have been withdrawn. However, the text of the Office Action includes a rejection under 35 U.S.C. § 102(b) to claims 15-39 are rejected under 35 U.S.C. § 102(b) as being anticipated by USPN 4,750,482 to Sieverding. Applicants have assumed for purposes of responding to the Office Action that the inclusion of the 35 U.S.C. § 102(b) rejection was inadvertent. Please advise if that is not the case, and a 35 U.S.C. § 102(b) rejection was intended.

In an abundance of caution, Applicants again argue that Sieverding fails to disclose a water-soluble or water-dispersible layer. Sieverding specifies that the adhesive is "water-insoluble." (see, e.g., Abstract and col. 7, line 61). Further, Sieverding fails to disclose any construction of a device in which the support layer is attached to the carrier layer on the surface opposite the adhesive layer, i.e. a construction of 1) support layer, 2) carrier layer, 3) adhesive layer.

Sieverding is concerned with a pressure sensitive adhesive that is "a soft, yet strong, rubber-like solid" that "absorbs moisture that cannot be squeezed out." Sieverding does not teach or suggest a single layer or combination of layers, each layer capable of dissolving or dispersing once in contact with water. In contrast to the Office Action's characterization, Sieverding specifies that the adhesive must be water-insoluble. In the uses contemplated by Sieverding (e.g., "a bandage, a burn or wound dressing, a sanitary napkin, an ostomy device . . ." as recited in col. 17 lines 20-27), a water-dispersible layer would be undesirable.

Because Seiverding fails to disclose every element of the claims, Applicants request that the rejections under 35 U.S.C. § 102(b) should be withdrawn.

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**Claim Rejections Under 35 U.S.C. § 103(a)**

Claims 1-5 and 7-16 are rejected under 35 U.S.C. § 103(a) as being obvious over USPN 5,196,202 to Konishi. Applicants respectfully traverse the rejection.

The present rejection of the pending claims does not set forth a case of *prima facie* obviousness. To establish a *prima facie* case of obviousness, there must be some suggestion or motivation, either in the reference or in the knowledge generally available to one of ordinary skill in the art to modify the reference; there must be a reasonable expectation of success; and the prior art reference must teach or suggest all the claim limitations. Moreover, the teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on Applicants' disclosure.

Konishi discloses at a minimum, a three layer construction that includes a drug release controlling layer, the drug reservoir layer, and the adhesive layer. Preferably, the device of Konishi is a four layer construction that also includes a drug impermeable layer between the drug reservoir layer and the adhesive layer. The construction is designed to provide controlled release dosage form in the oral cavity for a prolonged period of time. See col. 1, lines 50-53; col. 2, lines 33-46. Konishi fails to teach a "cold-water soluble or cold-water dispersible" carrier layer or adhesive layer.

Further, Konishi fails to disclose "a support layer releasably adhered to the second surface of the carrier" as recited in the independent claims. Konishi requires that all the layers in its device be permanently attached, i.e., "each of these layers is piled in order, glued and dried." (Col. 4, lines 3-14 and Example 1(E)). Assuming for purposes of argument that the drug release controlling layer was the support layer (which Applicants dispute), then the ability to releasably detach the drug release controlling layer would change, and potentially destroy, the function of the Konishi multilayer patch. Thus, Konishi fails to provide a suggestion or motivation to modify the reference to include a "cold-water soluble or cold-water dispersible layer" or "releasably adhered layer", or that a using a cold-water soluble layer or releasably adhered support layer would have a reasonable expectation of success.

The Examiner argues that Applicants fail to define "releasably adhered to the second surface of the carrier" and that no degree of release is recited in the claim. "Releasable" is defined as "intended or configured to be released." *The American Heritage Dictionary of the English Language* (4<sup>th</sup> Ed 2000). One of the skill in the art

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would understand that a releasable support layer is designed to be removed without impact or destruction to the remaining layers. In contrast, Konishi describes "glued and dried" layers, which would suggest maintaining the layers together (i.e., not releasable), and require force to separate the layers, if separation is even possible.

Claims 1, 4 and 6 are rejected under 35 U.S.C. § 103(a) as obvious over Konishi in view of USPN 5,688,776 to Bauer. The Examiner acknowledges that Konishi fails to teach arabinogalactan but relies on Bauer for that disclosure. As discussed above, Konishi at a minimum fails to disclose "cold-water soluble or cold-water dispersible layer" or "releasably adhered layer". Bauer teaches "polysaccharides which are crosslinked, and thus no longer water-soluble but are still biodegradable." (see Abstract). Bauer fails to teach or disclose a cold-water soluble/water dispersible carrier layer, cold-water soluble/water dispersible adhesive layer, or a support layer. Thus, the combination of Konishi and Bauer fails to teach all elements of the present invention. Applicants request that the rejections under 35 U.S.C. § 103(a) should be withdrawn.

#### Conclusion

In view of the arguments offered herein, Applicants respectfully submit that the Examiner's grounds for objection and rejection are overcome and respectfully solicit reconsideration and withdrawal of the rejections to place the application in condition for allowance.

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Respectfully submitted,

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